

104TH CONGRESS
1ST SESSION

S. 78

To establish a temporary program under which parenteral diacetylmorphine will be made available through qualified pharmacies for the relief of intractable pain due to cancer, and for other purposes.

IN THE SENATE OF THE UNITED STATES

JANUARY 4, 1995

Mr. INOUE introduced the following bill; which was read twice and referred to the Committee on Labor and Human Resources

A BILL

To establish a temporary program under which parenteral diacetylmorphine will be made available through qualified pharmacies for the relief of intractable pain due to cancer, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Compassionate Pain
5 Relief Act”.

6 **SEC. 2. FINDINGS.**

7 Congress finds that—

1 (1) cancer is a progressive, degenerative, and
2 often painful disease that afflicts one out of every
3 four persons in the United States and is the second
4 leading cause of death;

5 (2) in the progression of terminal cancer, a sig-
6 nificant number of patients experience levels of in-
7 tense and intractable pain that cannot be effectively
8 treated by presently available medication;

9 (3) the effect of such pain often leads to a se-
10 vere deterioration in the quality of life of the patient
11 and heartbreak for the family of the patient;

12 (4) the therapeutic use of parenteral
13 diacetylmorphine is not permitted in the United
14 States but extensive clinical research has dem-
15 onstrated that the drug is a potent, highly soluble
16 painkilling drug when properly formulated and ad-
17 ministered under the supervision of a physician;

18 (5) it is in the public interest to make paren-
19 teral diacetylmorphine available to patients through
20 controlled channels as a drug for the relief of intrac-
21 table pain due to terminal cancer;

22 (6) diacetylmorphine is successfully used in
23 Great Britain and other countries for relief of pain
24 due to cancer;

1 (7) the availability of parenteral
2 diacetylmorphine for the limited purposes of control-
3 ling intractable pain due to terminal cancer will not
4 adversely affect the abuse of illicit drugs or increase
5 the incidence of pharmacy thefts;

6 (8) the availability of parenteral
7 diacetylmorphine will enhance the ability of physi-
8 cians to effectively treat and control intractable pain
9 due to terminal cancer; and

10 (9) it is appropriate for the Federal Govern-
11 ment to establish a temporary program to permit
12 the use of pharmaceutical dosage forms of paren-
13 teral diacetylmorphine for the control of intractable
14 pain due to terminal cancer.

15 **SEC. 3. PARENTERAL DIACETYLMORPHINE PROGRAM.**

16 Title III of the Public Health Service Act (42 U.S.C.
17 241 et seq.) is amended by adding at the end the following
18 new part:

19 “PART O—COMPASSIONATE PAIN RELIEF

20 **“SEC. 399G. PARENTERAL DIACETYLMORPHINE.**

21 “(a) REGULATIONS.—

22 “(1) IN GENERAL.—Not later than three
23 months after the date of the enactment of this part,
24 the Secretary shall issue regulations establishing a
25 program (referred to in this section as the ‘pro-

1 gram') under which parenteral diacetylmorphine
2 may be dispensed from pharmacies for the relief of
3 intractable pain due to terminal cancer.

4 “(2) TERMINAL CANCER.—For purposes of this
5 section, an individual shall be considered to have ter-
6 minal cancer if there is histologic evidence of a ma-
7 lignancy in the individual and the cancer of the indi-
8 vidual is generally recognized as a cancer with a
9 high and predictable mortality.

10 “(b) MANUFACTURING.—Regulations established
11 under this section shall provide that manufacturers of par-
12 enteral diacetylmorphine for dispensing under the pro-
13 gram shall use adequate methods of, and adequate facili-
14 ties and controls for, the manufacturing, processing, and
15 packing of such drug to preserve the identity, strength,
16 quality, and purity of the drug.

17 “(c) AVAILABILITY TO PHARMACIES.—

18 “(1) REQUIREMENTS.—Regulations established
19 under this section shall require that parenteral
20 diacetylmorphine be made available only to phar-
21 macies that—

22 “(A) are hospital pharmacies or such other
23 pharmacies as the regulations specify;

24 “(B) are registered under section 302 of
25 the Controlled Substances Act (21 U.S.C. 822);

1 “(C) meet such qualifications as the regu-
2 lations specify; and

3 “(D) submit an application in accordance
4 with paragraph (2).

5 “(2) APPLICATION.—An application for paren-
6 teral diacetylmorphine shall—

7 “(A) be in such form and submitted in
8 such manner as the Secretary may prescribe;
9 and

10 “(B) contain assurances satisfactory to the
11 Secretary that—

12 “(i) the applicant will comply with
13 such special requirements as the Secretary
14 may prescribe respecting the storage and
15 dispensing of parenteral diacetylmorphine;
16 and

17 “(ii) parenteral diacetylmorphine pro-
18 vided under the application will be dis-
19 pensed through the applicant upon the
20 written prescription of a physician reg-
21 istered under section 302 of the Controlled
22 Substances Act (21 U.S.C. 822) to dis-
23 pense controlled substances in schedule II
24 of such Act (21 U.S.C. 812(2)).

1 “(3) INTENT OF CONGRESS.—It is the intent of
2 Congress that—

3 “(A) the Secretary shall primarily utilize
4 hospital pharmacies for the dispensing of paren-
5 teral diacetylmorphine under the program; and

6 “(B) the Secretary may distribute paren-
7 teral diacetylmorphine through pharmacies
8 other than hospital pharmacies in cases in
9 which humanitarian concerns necessitate the
10 provision of parenteral diacetylmorphine, a sig-
11 nificant need is shown for such provision, and
12 adequate protection is available against the di-
13 version of parenteral diacetylmorphine.

14 “(d) ILLICIT DIVERSION.—Regulations established
15 by the Secretary under this section shall be designed to
16 protect against the diversion into illicit channels of paren-
17 teral diacetylmorphine distributed under the program.

18 “(e) PRESCRIPTION BY PHYSICIANS.—Regulations
19 established under this section shall—

20 “(1) require that parenteral diacetylmorphine
21 be dispensed only to an individual in accordance
22 with the written prescription of a physician;

23 “(2) provide that a physician registered under
24 section 302 of the Controlled Substances Act (21
25 U.S.C. 822) may prescribe parenteral

1 diacetylmorphine for individuals for the relief of in-
2 tractable pain due to terminal cancer;

3 “(3) provide that any such prescription shall be
4 in writing; and

5 “(4) specify such other criteria for the prescrip-
6 tion as the Secretary may determine to be appro-
7 prium.

8 “(f) FEDERAL FOOD, DRUG, AND COSMETIC ACT.—
9 The Federal Food, Drug, and Cosmetic Act (21 U.S.C.
10 301 et seq.) and titles II and III of the Comprehensive
11 Drug Abuse Prevention and Control Act of 1970 (21
12 U.S.C. 801 et seq. and 951 et seq.) shall not apply with
13 respect to—

14 “(1) the importing of opium;

15 “(2) the manufacture of parenteral
16 diacetylmorphine; and

17 “(3) the distribution and dispensing of paren-
18 teral diacetylmorphine,

19 in accordance with the program.

20 “(g) REPORTS.—

21 “(1) BY THE SECRETARY.—

22 “(A) IMPLEMENTATION AND ACTIVITIES.—

23 “(i) IMPLEMENTATION.—Not later
24 than 2 months after the date of the enact-
25 ment of this part and every third month

1 thereafter until the program is established
2 under subsection (a), the Secretary shall
3 prepare and submit to the Committee on
4 Energy and Commerce of the House of
5 Representatives and the Committee on
6 Labor and Human Resources of the Senate
7 a report containing information on the ac-
8 tivities undertaken to implement the pro-
9 gram.

10 “(ii) ACTIVITIES.—Not later than 1
11 year after the date the program is estab-
12 lished under subsection (a) and annually
13 thereafter until the program is terminated
14 under subsection (h), the Secretary shall
15 prepare and submit to the committees de-
16 scribed in clause (i) a report containing in-
17 formation on the activities under the pro-
18 gram during the period for which the re-
19 port is submitted.

20 “(B) PAIN MANAGEMENT.—Not later than
21 6 months after the date of the enactment of
22 this part, the Secretary shall prepare and sub-
23 mit to the Committee on Energy and Commerce
24 of the House of Representatives and the Com-

mittee on Labor and Human Resources of the
Senate a report that—

“(i) describes the extent of research
activities on the management of pain that
have received funds through the National
Institutes of Health;

“(ii) describes the ways in which the
Federal Government supports the training
of health personnel in pain management;
and

“(iii) contains recommendations for
expanding and improving the training of
health personnel in pain management.

“(2) BY THE COMPTROLLER GENERAL.—Not
later than 56 months after the date on which the
program is established under subsection (a), the
Comptroller General of the United States shall pre-
pare and submit to the committees referred to in
paragraph (1)(A)(i) a report containing information
on the activities conducted under the program dur-
ing such 56-month period.

“(h) TERMINATION AND MODIFICATION.—

“(1) IN GENERAL.—The Secretary may at any
time later than 6 months after the date on which the
program is established under subsection (a), modify

1 the regulations required by subsection (a) or termi-
2 nate the program if in the judgment of the Secretary
3 the program is no longer needed or if modifications
4 or termination are needed to prevent substantial di-
5 version of the diacetylmorphine.

6 “(2) FINAL TERMINATION.—The program shall
7 terminate 60 months after the date the program is
8 established under subsection (a).”.

○